IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OPTRASCAN, INC., **Plaintiff,** **v.** **MORPHLE LABS, INC.,** **Defendant.**	**Court No. 1:24-cv-00649-JCG**

OPINION AND ORDER ON CLAIM CONSTRUCTION

[Providing claim construction for the patents in suit.]

Dated: November 20, 2025

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Choe-Groves, Judge: This matter is before the Court for claim construction of U.S. Patent No. 10,338,365 ("the '365 Patent"), and U.S. Patent No. 10,586,376 ("the '376 Patent") (collectively, "the Asserted Patents"). The Parties seek construction of the following terms and phrases from the '365 Patent: "slide basket

transfer assembly"; "slide transfer assembly"; "support base"; "slide scanning stage"; "slide transfer assembly configured to retrieve a slide from the slide basket transfer assembly, deliver the slide to the slide scanning stage of a slide scanner, and return the slide from the slide scanning stage to the slide basket transfer assembly"; and "slide holder." Am. Joint Claim Construction Chart ("Amended Joint Chart") (D.I. 66-1).

The Parties also seek construction of the following terms and phrases from the '376 Patent: "executing at least one cell segmentation process on the slide image through the processing device"; "analyzing the plurality of cells with at least one cell classification algorithm through the processing device"; "an automated slide scanning system and a processing device"; and "an automated method of predicting efficacy of immunotherapy approaches." Id.

Having considered the claim construction briefs and the arguments of counsel, the Court construes the disputed claim terms and phrases as set forth below.

BACKGROUND

Plaintiff OptraSCAN, Inc. ("Plaintiff" or "OptraSCAN") filed suit against Defendant Morphle Labs, Inc. ("Defendant" or "Morphle") for infringement of the '365 Patent and the '376 Patent. Am. Compl. ¶¶ 10–38 (D.I. 11). This Opinion

concerns the first step of the two-step infringement analysis, the construction of claims asserted in the '365 Patent and the '376 Patent.

The '365 Patent is titled "Slide Storage, Retrieval, Transfer, and Scanning System for a Slide Scanner" and was issued by the U.S. Patent and Trademark Office ("USPTO") on July 2, 2019. Am. Compl. at Ex. A ("'365 Patent") (D.I. 11-1). The '376 Patent is titled "Automated Method of Predicting Efficacy of Immunotherapy Approaches" and was issued by the USPTO on March 10, 2020. Id. at Ex. B ("'376 Patent") (D.I. 11-1). OptraSCAN is the exclusive owner and assignee of all rights, title, and interest in the Asserted Patents. Id. at ¶ 2.

Traditionally, pathologists analyzed samples with an optical microscope by manually loading each sample onto a glass slide, and would store, retrieve, or transfer each slide for scanning by hand. Id. at ¶ 12. Although OptraSCAN does not claim to have developed the first automated slide system or digital pathology system, it asserts that it invented a unique, consolidated system for microscopic slides with automated storage, retrieval, transfer, and scanning that is presented in the '365 Patent. Id. at ¶¶ 11–13. In addition, OptraSCAN developed an automated method for predicting the efficacy of immunotherapy treatments that is presented in the '376 Patent. Id. at ¶ 27. OptraSCAN's system can execute "whole slide scanning of biological specimens, image acquisition, image management, and

image analysis to detect histological and immunohistochemical biomarkers" within its scanner and without using third-party software. Id. at ¶¶ 27–28.

OptraSCAN alleges that Morphle has infringed and continues to directly infringe the '365 Patent. OptraSCAN states that Morphle's "MorphoLens 240" system for storing, retrieving, and transferring slides for scanning infringes at least Claim 1 of the '365 Patent. Id. at ¶¶ 15–25. Claim 1 of the '365 Patent states as follows:

> A slide storage, retrieval, transfer and scanning system for a slide scanner comprising:
>
> a slide scanning stage configured to receive a slide into a slide holder below a microscope objective and move the slide holder in relation to the microscope objective in order to scan the slide;
>
> a slide storage assembly configured to store at least one slide basket, wherein each of the at least one slide basket is configured to store a plurality of slides;
>
> a slide basket transfer assembly configured to retrieve and store the at least one slide one slide basket from and into the slide storage assembly, respectively;
>
> a slide transfer assembly configured to retrieve a slide from the slide basket transfer assembly, deliver the slide to the slide scanning stage of a slide scanner, and return the slide from the slide scanning stage to the slide basket transfer assembly;
>
> a slide basket holder of the slide basket transfer assembly being configured to move vertically along a Z axis in order to transfer a slide basket from the slide storage assembly to the slide transfer assembly; and
>
> a support base of the slide transfer assembly being configured to move horizontally in an X-Y plane in order to transfer a slide from the slide basket transfer assembly to the slide scanning stage of the slide scanner, wherein the Z axis is perpendicular to the X-Y plane.

'365 Patent at 13:50–14:9.

With regard to the '376 Patent, OptraSCAN alleges that Morphle's slide reader product, the "HemoLens 16," infringes at least Claim 1 of the '376 Patent because Morphle's product is a slide scanner that includes both an image acquisition unit and a processor that can analyze cells and compute a treatment efficacy score. Am. Compl. at ¶¶ 30–38. Plaintiff asserts that a similar product, the "MorphoLens 240," also infringes the '376 Patent. Id. at ¶ 35. Claim 1 of the '376 Patent states as follows:

> An automated method of predicting efficacy of immunotherapy approaches comprises the steps of:
>
> (A) providing an automated slide scanning system and a processing device, wherein the automated slide scanning system comprises an image acquisition unit, and wherein the automated slide scanning system is electronically connected to the processing device;
>
> (B) receiving a sample slide through the automated slide scanning system, wherein a tissue sample is mounted to the sample slide;
>
> (C) acquiring at least one slide image of the tissue sample through the image acquisition unit;
>
> (D) executing at least one cell segmentation process on the slide image through the processing device in order to identify a plurality of cells from the slide image;
>
> (E) analyzing the plurality of cells with at least one cell classification algorithm through the processing device in order to identify a tumor cell percent positivity value and an immune cell percent positivity value; and
>
> (F) calculating a treatment efficacy score from the tumor cell percent positivity value and the immune cell percent positivity value.

'376 Patent at 8:7–28.

The Parties filed a Joint Claim Construction Chart ("Joint Chart") and a Joint Claim Construction Brief ("Joint Brief"). Joint Chart (D.I. 51); Joint Br. (D.I.

65). After reaching further agreement on the construction of three terms, the Parties filed the Amended Joint Chart. Am. Joint Chart. The Court held a claim construction hearing on October 20, 2025, and the Parties did not call expert witnesses. See Oral Order (Sept. 18, 2025) (D.I. 67).

CLAIM CONSTRUCTION STANDARD

When the meaning of a patent claim's language is disputed, the court must construe the claim as a matter of law. Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996). "[T]he construction of a patent, including terms of art within its claim, is exclusively within the province of the court." Markman, 517 U.S. at 372. "The purpose of claim construction is to 'determin[e] the meaning and scope of the patent claims asserted to be infringed.'" O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co., 521 F.3d 1351, 1360 (Fed. Cir. 2008) (citing Markman, 52 F.3d at 976).

"The patent is a fully integrated written instrument." Markman, 52 F.3d at 978. For the purpose of claim construction, "[a] court should look first to the intrinsic evidence of record, i.e., the patent itself, including the claims, the specification and, if in evidence, the prosecution history." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996) (citing Markman, 52 F.3d at 979). "The words of a claim are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art when read in the

context of the specification and prosecution history." Thorner v. Sony Comput. Ent. Am. LLC, 669 F.3d 1362, 1365 (Fed. Cir. 2012) (citing Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc)).

Limitations from dependent claims, the specification, and embodiments will not be read into the claims. "The doctrine of claim differentiation [ ] creates a presumption that [ ] dependent claim limitations are not included in the independent claim." GE Lighting Sols., LLC v. AgiLight, Inc., 750 F.3d 1304, 1310 (Fed. Cir. 2014) (citation omitted). Limitations found in the specification are not imposed into the claims. Phillips, 415 F.3d at 1323–24. In the same vein, "[i]t is improper to read limitations from a preferred embodiment described in the specification—even if it is the only embodiment—into the claims absent a clear indication in the intrinsic record that the patentee intended the claims to be so limited." GE Lighting Sols., 750 F.3d at 1309 (citation omitted) (discussing a figure as a "depicted embodiment").

DISCUSSION

I. Undisputed Terms

The Court acknowledges that the Parties agree on the construction of four phrases from Claims 1 and 7 of the '376 Patent: (1) "whole slide image"/"a whole slide image of the sample slide" from Claims 1 and 7 shall mean "an image of the entire tissue sample mounted on a slide"; (2) "tumor cell percent positivity value"

from Claim 1 shall mean "the number of tumor cells divided by the total number of cells identified, expressed as a percentage"; (3) "immune cell percent positivity value" from Claim 1 shall mean "the number of immune cells divided by the total number of cells identified, expressed as a percentage"; and (4) "calculating a treatment efficacy score from the tumor cell percent positivity value and the immune cell percent positivity value" from Claim 1 shall mean "calculating a numeric score that indicates how effective a treatment is, using as inputs for the calculation both the tumor cell percent positivity value and the immune cell percent positivity value." Joint Br. at 1; Joint Letter Regarding Am. Claim Construction Chart (D.I. 66).

The Court accepts and adopts these constructions without further discussion.

II. Disputed Terms

The Parties dispute the necessity of construction for six claims terms that appear in Claims 1 and 7 of the '365 Patent, and four terms that appear in Claims 1 and 4 of the '376 Patent. The Court examines the disputed claim terms and the Parties' proposed constructions in turn.

a. '365 Patent

At the outset, the Court addresses Defendant's general reference to means-plus-function claim limitations governed by 35 U.S.C. § 112(f). Joint Br. at 5–6

(citing Williamson v. Citrix Online, LLC, 792 F.3d 1339, 1351–52 (Fed. Cir. 2015)).

A means-plus-function claim exists when a claim term is drafted in a manner that invokes 35 U.S.C. § 112(f), which states:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

35 U.S.C. § 112(f); see Williamson, 792 F.3d at 1347.

The court in Williamson recognized Congress' intent to allow patentees to state a claim limitation by reciting a function to be performed rather than the structure for performing that function, while including constraints on how such a limitation should be construed, particularly by restricting the scope of coverage to only the structure, materials, or acts described in the specification as corresponding to the claimed function or equivalents thereof. Id. at 1347–48 (citing Northrop Grumman Corp. v. Intel Corp., 325 F.3d 1346, 1350 (Fed. Cir. 2003)).

When disputed claim terms do not use the word "means," there is a rebuttable presumption that § 112(f) does not apply. Id. at 1348. To overcome that presumption, a defendant must demonstrate by a preponderance of the evidence that the claim terms fail to recite sufficiently definite structure or else recite function without reciting sufficient structure for performing that function.

Id. at 1349 (citation omitted). Claim limitations that use a non-structural placeholder term as a substitute for the word "means for" may overcome the presumption. Id. at 1350–51 ("Generic terms such as 'mechanism,' 'element,' 'device,' and other nonce words that reflect nothing more than verbal constructs may be used in a claim in a manner that is tantamount to using the word 'means' because they 'typically do not connote sufficiently definite structure' and therefore may invoke § 112 . . . ."") (citation omitted).

If the presumption that § 112(f) does not apply is overcome, the court must undertake a two-step inquiry to determine whether the terms are indefinite. Id. at 1351. First, the court must identify the claimed function. Id. Then the court must determine what structure, if any, disclosed in the specification corresponds to the claimed function. Id. Structure disclosed in the specification shall be regarded as "corresponding structure" if the intrinsic evidence clearly links or associates that structure to the function recited in the claim. Id. at 1352. If the specification does not disclose adequate corresponding structure, the claim is indefinite. Id.

Despite invoking this statute, Defendant does not argue or propose a means-plus-function construction for any disputed term in the '365 Patent, and the Court concludes that the disputed terms are not drafted as means-plus-function limitations subject to 35 U.S.C. § 112(f). None of the terms at issue use the word "means." See '365 Patent at 13:50–14:9. The words "assembly," "stage," or

"base" could appear to operate such as the generic nonce words that are used as substitutes for the term "means" if provided in isolation. Williamson, 325 F.3d at 1350–51. However, the full terms are "slide basket transfer assembly," "slide transfer assembly," "slide scanning stage," and "support base." See '365 Patent at 13:50–14:9. Each of these claim terms are modified such that they connote sufficiently definite structure and there is no indication that these terms would not be reasonably well understood as designating structure to one of ordinary skill in the art. See Williamson, 325 F.3d at 1348–51.

The Court turns now to the Parties' proposed constructions.

i. "slide basket transfer assembly"

Independent Claim 1 of the '365 Patent recites a "slide basket transfer assembly configured to retrieve and store the at least one slide basket from and into the slide storage assembly, respectively[.]" '365 Patent at 13:60–62.

Plaintiff asserts that the term "slide basket transfer assembly" should be construed to mean "structure sufficient to move a slide basket into and out of the slide storage assembly." Joint Br. at 8. Plaintiff avers that its construction captures the '365 Patent's description and addresses the relationship between the slide basket holder and the slide storage assembly. Id. at 9–10. Plaintiff argues that Morphle's construction includes the movement limitations of the slide basket holder but construes them in error. Id. While Claim 1 recites that the slide basket

holder is configured to move vertically along a Z axis, Plaintiff argues that the possibility of vertical movement does not necessitate the presence of a vertical structure, only structure that could move vertically. Id. In the alternative, Plaintiff suggests that if construction requires reference to the slide basket holder, the Court should construe it as "a component of the slide basket transfer assembly that can move vertically along a Z axis." Id.

Defendant asserts that the Court should construe "slide basket transfer assembly" to mean "a component that includes a vertical structure which enables movement of a slide basket holder along the vertical structure at the Z axis." Id. at 8. Defendant avers that although the specification includes general statements that the slide basket holder is not limited in movement or structure, the patentee later amended the claims during prosecution to disclaim such scope and require vertical movement along a Z axis. Id. at 11–14.

While specific terms may be at the center of claim construction, the context provided by the surrounding claim language can inform the ordinary meaning of the terms. ACTV, Inc. v. The Walt Disney Co., 346 F.3d 1082, 1088 (Fed. Cir. 2003). Courts should not construe claims restrictively unless the patentee demonstrated a clear intention to limit the claim scope. Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1117 (Fed. Cir. 2004). Claim scope may be limited when the claims, read in view of the specification, do not

permit the broad construction proposed by the patentee or suggest that the patentee has limited the scope of the claims. Profectus Tech. LLC v. Huawei Techs. Co., 823 F.3d 1375, 1381–83 (Fed. Cir. 2016). The prosecution history can also inform the meaning of the claim language when it demonstrates how the inventor understood the invention and whether the inventor narrowed the scope of the claims during prosecution. Phillips, 415 F.3d at 1317.

The prosecution history indicates that the patentee amended the claims during prosecution and limited the scope of the slide basket holder such that Claim 1 now describes "a slide basket holder of the slide basket transfer assembly being configured to move vertically along a Z axis in order to transfer a slide basket from the slide storage assembly to the slide transfer assembly." See Joint Br. at 12 (citing Amendment/Request for Reconsideration-After Non-Final Rejection (Apr. 3, 2019), Ex. A at 2). The specification states that "the direction the slide basket holder [ ] traverses should not necessarily be limited to the vertical direction, and different configurations of the present invention may comprise different arrangements in terms of the direction of travel of the slide basket holder [ ]." '365 Patent at 4:16–20. However, the plain language of the amended claim language disclaims such alternate arrangements by limiting the scope of the slide basket holder to vertical movement. Id. at 14:1–4. The context provided by the "slide basket holder" claim language and the prosecution history informs the construction

of "slide basket transfer assembly" because the slide basket holder is a component of the slide basket transfer assembly, and therefore the structure of the slide basket transfer assembly must include the potential for vertical movement along a Z axis. See id.; Phillips, 415 F.3d at 1317; ACTV, Inc., 346 F.3d at 1088. The '365 Patent uniformly describes the slide basket transfer assembly as including the slide basket holder, depicts a vertical track of the slide basket transfer assembly that could enable vertical movement, and discusses an alternative embodiment in which the slide basket transfer assembly "comprises a vertical rod that enables movement of the slide basket holder [ ] in a vertical manner along the rod at the Z axis [ ]." See '365 Patent at 14:1–4, 7:65–8:3, Fig. 3.

"[T]he standard construction rule [is] that a term can be defined only in a way that comports with the instrument as a whole." Markman, 517 U.S. at 389. The '365 Patent teaches that the slide basket transfer assembly includes a slide basket holder, which requires vertical movement and vertical structure, though the exact configuration of the vertical structure is not limited. Accordingly, the Court adopts Defendant's proposed construction and construes "slide basket transfer assembly" as "a component that includes a vertical structure which enables movement of a slide basket holder along the vertical structure at the Z axis."

ii. "slide transfer assembly"

Claim 1 recites a "slide transfer assembly configured to retrieve a slide from the slide basket transfer assembly, deliver the slide to the slide scanning stage of a slide scanner, and return the slide from the slide scanning stage to the slide basket transfer assembly[.]" '365 Patent at 13:63–67. Defendant asserts that the Court should construe the term "slide transfer assembly" to mean "a structure that moves in space and holds or grasps an individual microscope slide." Joint Br. at 20. Plaintiff asserts that the term "slide transfer assembly should be construed to mean "structure sufficient to move a slide between the slide basket transfer assembly and the slide scanning stage." Id.

Plaintiff argues that the inclusion of "grasping" or "holding" in Defendant's proposed construction is not required by the language of the claim and reads in a limitation from Dependent Claim 10, which recites a "slide grasping mechanism." Id. at 22–23, 28; see '365 Patent at 15:29–32. Plaintiff avers that in the absence of clear disavowal, the slide transfer assembly limitation does not require movement of an individual slide and must be construed broadly enough to contemplate movement of a single slide or of a slide basket containing multiple slides. Joint Br. at 21.

Defendant avers that its construction is consistent with the claim language and the specification because the movement of a single microscope slide is

emphasized throughout the '365 Patent. Id. at 25 (citing '365 Patent 4:52–67, 5:1–34, 5:64–67). Defendant concedes that how the slide transfer assembly moves a slide "may be somewhat flexible," but that regardless of the form it takes, the claim language and the specification require the structure to transfer only a single slide. Id. at 25, 29.

The scope of a claim may be limited when the claims, read in view of the specification, do not permit the broad construction proposed by the patentee or suggest that the patentee has limited the scope of the claims. Profectus Tech. LLC, 823 F.3d at 1381–83 (concluding that "mountable" meant "having a feature for mounting" rather than "capable of mounting" because the specification described mounting in every embodiment); see also Watts v. XL Sys., Inc., 232 F.3d 877, 882 (Fed. Cir. 2000). While the language of the claims read in isolation may not obviate limiting a claim, the general descriptions of the invention in the specification may indicate that the only reasonable interpretation of a claim is one that limits its scope. Rembrandt Patent Innovations, LLC v. Apple, 716 Fed. Appx. 965, 971 (Fed. Cir. 2017) (concluding that a component required automatic recovery, despite claim language read in isolation not indicating that, because the abstract and specification characterized the component as automated).

Restrictions in scope may also be evidenced by the phrasing of the claims, and the presumption that "a" or "an" means "one or more" may be overcome when

the language of the claims, the specification, or the prosecution history evidence an intent to limit "a" or "an" to "one." KCJ Corp. v. Kinetic Concepts, Inc., 223 F.3d 1351, 1356 (Fed. Cir. 2000) ("This court has repeatedly emphasized that an indefinite article 'a' or 'an' in patent parlance carries the meaning of 'one or more' in open-ended claims containing the transitional phrase 'comprising.'"); but see Baldwin Graphic Sys., Inc. v. Siebert, Inc., 512 F.3d 1338, 1343 (Fed. Cir. 2008) ("An exception to the general rule that 'a' or 'an' means more than one only arises where the language of the claims themselves, the specification, or the prosecution history necessitate a departure from the rule."); Harari v. Lee, 656 F.3d 1331, 1341–42 (Fed. Cir. 2011) (concluding that the claim language distinguished singular from plural by using "a" to refer to "one," and "at least" to refer to "more than one"); Insituform Techs., Inc. v. Cat Contracting, Inc., 99 F.3d 1098, 1105–06 (Fed. Cir. 1996) (concluding that the only reasonable construction limited the scope to a single vacuum cup based on specification and because "claim 1 refers to 'a cup' and 'the cup' repeatedly, suggesting that only one cup is involved.")

The Court concludes that the language of the claims and the intrinsic record indicate that the patentee limited the scope of the slide transfer assembly to movement of a single slide. Claim 1 describes the slide storage assembly as configured to store "at least one slide basket," but later recites that the slide basket holder is configured to transfer "a slide basket." '365 Patent 13:57–59, 14:1–3.

The slide storage assembly limitation describes the slide basket as configured to hold "a plurality of slides," but the remaining references to microscope slides use "a slide" and "the slide" repeatedly. Id. at 13:53, 13:63, 14:7; see Harari, 656 F.3d at 1341–42; Insituform Techs., Inc., 99 F.3d at 1105–06. These phrasing choices indicate that a departure from the general rule that "a" means "more than one" is warranted because the varied phrasing is meaningless or redundant otherwise. See Baldwin Graphic Sys., Inc., 512 F.3d at 1343.

The abstract and written description provide further support for limiting the scope of the slide transfer assembly to movement of an individual slide. See id.; Rembrandt Patent Innovations, LLC, 716 Fed.Appx. at 971. The '365 Patent's abstract explains that "a slide transfer assembly retrieves *a single slide* from the basket and delivers the slide to a slide scanning stage for scanning." '365 Patent at Abstract (emphasis added). The specification states generally that "the slide transfer assembly functions to retrieve *an individual slide* . . . ." Id. at 4:53–56 (emphasis added). The specification contemplates the possibility of various embodiments and forms of the slide transfer assembly but states that "in essence, the basic requirements of the slide transfer assembly [ ] are to be able to move in space in order to grasp *an individual slide* [ ] from the slide basket transfer assembly [ ], remove the slide [ ], move the slide [ ] to the slide scanning stage [ ], and place the slide [ ] into an appropriate position for scanning on the slide

scanning stage [ ]." Id. at 4:61–67 (emphasis added). These descriptions limit the scope of the slide transfer assembly consistently and repeatedly to movement of a single slide. See id. at 4:53–67, 5:64–67; see also Profectus Tech. LLC, 823 F.3d at 1381–83. Plaintiff argues that the structure and functionality of the slide transfer assembly are not limited, but Plaintiff cannot identify an example in the intrinsic record of the patent contemplating a situation when this component moves more than a single slide. Joint Br. at 26. Plaintiff argues further that limiting the slide transfer assembly to movement of one slide would be improper because there was no clear disclaimer or redefinition of the term. Joint Br. at 22–23, 26–27. These arguments are unpersuasive because disclaimer does not require express statements identifying the surrendered claim scope and can be implicit if it is still sufficiently clear. Rembrandt Patent Innovations, LLC, 716 Fed.Appx. at 972. It is clear that the claim language and the written descriptions throughout the '365 patent indicate uniformly that the slide transfer assembly moves an individual slide.

Regarding how the slide is moved, the Court concludes that this aspect of the claim term should be construed broadly to avoid reading in limitations from the embodiments and dependent claims. See Phillips, 415 F.3d at 1323–24; GE Lighting Sols., 750 F.3d at 1310. The claim language and the specification do not consistently refer to the slide transfer assembly as "holding" or "grasping" the slide, but describe the movement using a variety of words, including "retrieving,"

"placing," or "delivering." '365 Patent at 13:63–67, 4:53–67. Broader construction also avoids redundancy with the "slide grasping mechanism" described in Dependent Claim 10. See Joint Br. at 22–23, 28–29. Finally, Plaintiff's construction captures more accurately the relationship between the slide transfer assembly and the surrounding structures as indicated by the claim language. See Joint Br. at 20; '365 Patent at 13:63–67; Markman, 517 U.S. at 389 ("the standard construction rule [is] that a term can be defined only in a way that comports with the instrument as a whole.").

The Court construes "slide transfer assembly" to mean "structure sufficient to move an individual slide between the slide basket transfer assembly and the slide scanning stage."

iii. "Support Base"

Claim 1 recites a "support base of the slide transfer assembly being configured to move horizontally in an X-Y plane in order to transfer a slide from the slide basket transfer assembly to the slide scanning stage of the slide scanner wherein the Z axis is perpendicular to the X-Y plane." '365 Patent at 14:5–9. Defendant asserts that the Court should construe the term "support base" to mean "a structure that supports an individual microscope slide." Joint Br. at 32. Plaintiff asserts that "support base" should be construed to mean "structure in the slide transfer assembly that moves horizontally in an X-Y plane." Id. The Parties focus

their arguments on whether the slide transfer assembly moves an individual slide. Id. at 32–39. Because the Court concluded earlier that the slide transfer assembly moves a single slide, the Court will not address repeated arguments on this issue.

Aside from Claim 1, the claims of the '365 Patent mention the term "support base" only in Dependent Claim 10, which recites a configuration of the invention wherein a "slide transfer assembly comprising a support base" has a "slide support" positioned on the support base and a slide grasping mechanism is "integrated onto the support base around the slide support . . . ." '365 Patent at 15:29–38. The specification states that in some embodiments "the slide transfer assembly [ ] may comprise a support base," while in other embodiments "the support base [ ] of the slide basket transfer assembly [ ] is configured to move horizontally in an X-Y plane in order to transfer a slide [ ] from the slide basket transfer assembly [ ] to the slide scanning stage [ ] of the slide scanner, wherein the X-Y plane is perpendicular to the Z axis [ ]." Id. at 5:1–2; 6:2–8. The specification includes depictive embodiments of the relation between the support base and the slide transfer assembly in Figures 4 and 5. Id. at Figs. 4–5.

The Court concludes that Plaintiff's proposed construction is consistent with the plain and ordinary meaning of "support base" in the context of the entire patent, including the specification and Figures 4 and 5. The Court adopts

Plaintiff's proposed construction and construes "support base" as "structure in the slide transfer assembly that moves horizontally in an X-Y plane."

iv. "Slide scanning stage"

Claim 1 recites "a slide scanning stage configured to receive a slide into a slide holder below a microscope objective and move the slide holder in relation to the microscope objective in order to scan the slide[.]" Id. at 13:53–56. Defendant asserts that the Court should construe the term "slide scanning stage" to mean "a platform on which an individual microscope slide is placed." Id. at 39. Plaintiff asserts that the term "slide scanning stage" does not require construction and should be given its plain and ordinary meaning. Id. at 39–40. In the alternative, Plaintiff proposes that "slide scanning stage" should be construed to mean "structure that facilitates the scanning of at least one slide." Id.

Dependent Claims 12–15 discuss several configurations for positioning and adjusting a slide on the slide scanning stage, and the specification includes depictive embodiments in Figures 1 and 7–9. '365 Patent at Figs. 1, 7–9, 15:60–17:2. The specification states that "[s]canning multiple slides [ ] on the stage is especially challenging because orthogonality of the optical system is typically accomplished on a single slide position," but provides that the slide scanning stage embodiments include a "manufacturable method to hold multiple slides," and describes this configuration. Id. at 12:21–22, 13:17–42.

Considering the language of the claim and the evidence in the intrinsic record, Defendant's proposed construction is too narrow because it incorporates a limitation from the slide transfer assembly unnecessarily and therefore excludes the embodiments that permit scanning multiple slides on the slide scanning stage. See Nobel Biocare Services AG v. Instradent USA, Inc., 903 F.3d 1365, 1381 (Fed. Cir. 2018) ("there is a strong presumption against a claim construction that excludes a disclosed embodiment") (citation omitted). Although the Court concluded previously that the '365 Patent limits the slide transfer assembly to movement of an individual slide to the slide scanning stage, it seems possible that the slide transfer assembly could make multiple trips to a slide scanning stage configured to achieve the scanning of multiple slides. See '365 Patent at 12:22–23, 13:17–42. The Court declines to adopt Plaintiff's alternative construction in its entirety because the phrase "facilitates the scanning" could introduce confusion to a jury as to whether the slide scanning stage accomplishes the scanning rather than a viewer using the microscope objective. See id. at 2:51–56, 6:19–23.

For the foregoing reasons, the Court construes "slide scanning stage" as "structure on which at least one slide is placed for scanning."

v. "slide transfer assembly configured to retrieve a slide from the slide basket transfer assembly, deliver the slide to the slide scanning stage of a slide scanner, and return the slide from the slide scanning stage to the slide basket transfer assembly"

Claim 1 recites a "slide transfer assembly configured to retrieve a slide from the slide basket transfer assembly, deliver the slide to the slide scanning stage of a slide scanner, and return the slide from the slide scanning stage to the slide basket transfer assembly[.]" Id. at 13:63–67.

Defendant asserts that the Court should construe this limitation as "the slide transfer assembly is able to retrieve an individual microscope slide from the slide basket transfer assembly, deliver the same individual microscope slide to the slide scanning stage of the slide scanner, and return the same individual microscope slide to the slide basket transfer assembly." Joint Br. at 46. Plaintiff asserts that this limitation does not require construction and should be given its plain and ordinary meaning because the Parties proposed constructions for the term "slide transfer assembly" previously. Id. at 46. In the alternative, Plaintiff proposes that the Court should construe the limitation to mean "structure of the 'slide transfer assembly' that moves at least one slide from the 'slide basket transfer assembly' to the 'slide scanning stage' and back to the 'slide basket transfer assembly.'" Id.

The Parties agree that construction turns on whether the "slide transfer assembly" limitation requires movement of an individual slide and reference their previous arguments on this issue. Id. at 47–48.

The Court concluded previously that the slide transfer assembly moves a single slide from the slide basket transfer assembly to the slide scanning stage because the claim language suggests that "a slide" refers to one and only one slide. See '365 Patent at 13:51–14:9; Baldwin Graphic Sys., Inc., 512 F.3d at 1343; Harari, 656 F.3d at 1341–42. The general descriptions of the invention contained in the abstract and specification indicate further that the only reasonable interpretation of the claim is one that limits the scope to movement of an individual slide. See '365 Patent at Fig. 2, 4:53–67, 5:64–67; Insituform Techs., Inc., 99 F.3d at 1105–06; Rembrandt Patent Innovations, LLC, 716 Fed.Appx. at 971–72.

Defendant's proposed construction of the present limitation is consistent with the language of the claims, the intrinsic record, and the Court's earlier construction of "slide transfer assembly." Accordingly, the Court construes "slide transfer assembly configured to retrieve a slide from the slide basket transfer assembly, deliver the slide to the slide scanning stage of a slide scanner, and return the slide from the slide scanning stage to the slide basket transfer assembly" to mean "the slide transfer assembly is able to retrieve an individual microscope slide from the slide basket transfer assembly, deliver the same individual microscope

slide to the slide scanning stage of the slide scanner, and return the same individual microscope slide to the slide basket transfer assembly."

vi. "slide holder"

Claim 1 recites "a slide scanning stage configured to receive a slide into a slide holder below a microscope objective and move the slide holder in relation to the microscope objective in order to scan the slide[.]" '365 Patent at 13:53–56. Defendant asserts that the Court should construe the term "slide holder" to mean "a structure that holds a single microscope slide securely in place for scanning." Joint Br. at 48. Plaintiff asserts that this term does not require construction and should be given its plain and ordinary meaning. Id. In the alternative, Plaintiff asserts that the Court should construe the limitation to mean "a structure that can hold at least one slide," arguing that Defendant's proposed construction is improper because it limits the slide holder to holding one slide and reads in limitations from Dependent Claim 12. Id. at 49–50.

Limitations from dependent claims, the specification, and embodiments will not be read into the claims generally. GE Lighting Sols., 750 F.3d at 1309–10. A dependent claim that adds a particular limitation creates a presumption that the limitation in question is not present in the independent claim. Phillips, 415 F.3d at 1315 (citation omitted). To avoid rendering the dependent claim redundant, the

independent claim should be construed to have a broader scope. Id. at 1324 (citing Dow Chem. Co. v. United States, 226 F.3d 1334, 1341–42 (Fed. Cir. 2000)).

Dependent Claim 12 recites a configuration of the slide scanning stage that comprises "a slide securing mechanism . . . wherein the slide securing mechanism secures a slide within the slide holder[.]" '365 Patent at 15:60–16:4. The specification's descriptions of the slide scanning stage provide that in some embodiments, a "slide securing mechanism" may be used to secure a slide such that the slide does not move and contemplates "a variety of configurations that produce the end result of holding a slide securely in place . . . ." Id. at 6:23–24, 6:40–44. In describing how the slide scanning stage could be configured to scan multiple slides, the specification contemplates use of a "tray based slide holder" or an embodiment that uses machining to modify the stage to accommodate multiple slides. Id. at 13:19–42. Depictive embodiments of the slide holder are included in Figures 7 and 8. Id. at Figs. 7–8.

Defendant's proposed construction requires the slide holder to have a "secure" hold. Joint Br. at 48. The word "secure" does not appear in the language of Claim 1 to describe the slide holder. See '365 Patent 13:53–56. The context provided by Dependent Claim 12 and the embodiments in the specification indicate further that the secure holding limitation is not present in the independent claim. The Court will construe "slide holder" more broadly to avoid rendering Dependent

Claim 12 redundant and to avoid reading in limitations from the embodiments. See GE Lighting Sols., 750 F.3d at 1309–10; Phillips, 415 F.3d at 1323.

Defendant's proposed construction also requires the slide holder to hold a single microscope slide. Joint Br. at 48. The Court found previously that the slide scanning stage can be configured to scan multiple slides and declined to adopt a proposed construction that read out this embodiment. Here, the Court rejects Defendant's proposed construction for similar reasons. Neither the general descriptions of the invention, the abstract, nor the embodiments indicate that the quantity of slides placed on the slide scanning stage and held by the slide holder is limited to one slide in all configurations. Rather, the specification contemplates that more than one slide can be placed on the slide scanning stage and the slide holding parts can be assembled around this configuration. See '365 Patent at 13:19–42. The Court will construe "slide holder" more broadly to avoid reading out this embodiment. See Nobel Biocare Services AG, 903 F.3d at 1381.

The Court construes "slide holder" to mean "a structure that holds at least one slide in place for scanning."

b. ’376 Patent

i. “executing at least one cell segmentation process on the slide image through the processing device . . .”

Independent Claim 1 of the ’376 Patent recites “[a]n automated method of predicting efficacy of immunotherapy approaches compris[ing] the steps of . . . executing at least one cell segmentation process on the slide image through the processing device in order to identify a plurality of cells from the slide image[.]” ’376 Patent at 8:19–21. Defendant asserts that the Court should construe the phrase “executing at least one cell segmentation process on the slide image through the processing device” under § 112(f) and should hold that the claim term is indefinite for lack of sufficient structure. Joint Br. at 62. Defendant argues that the word “executing” is a generic nonce word that does not identify the structure or acts necessary to carry out the cell segmentation and identification step, and therefore the claim language is a means-plus-function limitation. Id. at 64–68, 72–74.

Plaintiff asserts that “executing at least one cell segmentation process on the slide image through the processing device” should not be construed under § 112(f), and that the plain and ordinary meaning should apply. Id. at 62–63, 68–71. Because there is no actual dispute over the construction of the claim language, no construction is necessary at this time. Rather, the issue here is whether the phrase

"executing at least one cell segmentation process on the slide image through the processing device" is rendered indefinite and therefore invalid by the requirements of § 112(f).

Step-plus-functions and means-plus-functions are types of claim limitations that arise under § 112(f). Means-plus-function limitations relate to apparatus claims typically and arise when the drafter recites a "means for" performing a function rather than reciting the structure that performs the function. O.I. Corp. v. Tekmar Co., 115 F.3d 1576, 1582–83 (Fed. Cir. 1997). A step-plus-function limitation may arise in method claims when a claim recites a "step for" performing a function without providing the acts that accomplish the function. Id. When interpreting the language of § 112(f) to determine whether such a limitation is present, the United States Court of Appeals for the Federal Circuit ("CAFC") held that "structure and material go with means, acts go with steps." Id. The CAFC cautioned against construing every "-ing" gerund as a step-plus-function limitation and rejected the recitation of a function in the preamble of a claim as a reason for construing the individual claim limitations as step-plus-function. Id. As method claims must recite the steps of the method, the preambular words "the method comprises the steps of" do not convert each element into a step-plus-function form or create the presumption that that each element takes that form. Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc., 381 F.3d 1371, 1381–82 (Fed. Cir.

2004). Rather, the absence of "step for" in each of the claim elements invokes the presumption that § 112(f) was not intended to apply. Id.

Due to a dearth of cases interpreting method claims as employing step-plus-function limitations, it is unclear how to distinguish an act from a function. See Seal-Flex, Inc. v. Athletic Track and Court Const., 172 F.3d 836, 848–49, 852 (Fed. Cir. 1999). An oft-cited approach proposes that the "underlying function" of a method claim should correspond to what that element accomplishes in relationship to what the other claim elements and the claim overall accomplish. See id. at 849–50 (Rader, J., concurring). An "act" should correspond to how the function is accomplished. Id.

Here, Claim 1 of the '376 Patent is a method claim and the Court reviews whether the relevant claim language includes a step-plus-function limitation. See O.I. Corp., 115 F.3d at 1582–83. The inclusion of "steps of" in the preamble, and the exclusion of "step for" in each of the claim elements indicate that Claim 1 and the disputed claim language are not subject to the constraints of § 112(f). See Cardiac Pacemakers, Inc., 381 F.3d at 1381–82.

Defendant's contrary arguments conflate aspects of a means-plus-function determination with a step-plus-function determination. To support its contention that the disputed claim language is a means-plus-function limitation subject to § 112(f), Defendant cites to the portion of Williamson, a means-plus-function case,

where the CAFC concluded that the presumption that claim language lacking the word "means" is not subject to § 112(f) should not be characterized as "strong." Joint Br. at 64 (citing Williamson, 792 F.3d at 1348–49). The Williamson court did not extend this holding to step-plus-function claims, as Defendant contends. The only reference to a step-plus-function analysis under § 112(f) occurs when the Williamson court, while collecting means-plus-function cases, notes in passing that one such case cited another case "involving the different term 'step for' and the unusual circumstances in which [§ 112(f)] relates to the functional language of a method claim." Williamson, 792 F.3d at 1348–49 (citing Masco Corp. v. United States, 303 F.3d 1316, 1327 (Fed. Cir. 2002)). This is not support sufficient for Defendant's contention that "there is a heightened burden for showing that a claim term is a means-plus-function limitation where the words 'means' or 'step for' are not used." Joint Br. at 64.

Defendant argues next that "executing" is a nonce term for what is required to achieve the claim's cell segmentation process and that the use of this term overcomes the presumption that § 112(f) does not apply. Joint Br. at 64–65. Although nonce terms are found often in cases interpreting apparatus claims that employ means-plus-function limitations, neither Defendant, nor this Court, can identify any generic placeholder words that have been recognized as alternatives for "step for" and overcome the presumption that the method claim here is not a

step-plus-function limitation subject to § 112(f). See Williamson, 792 F.3d at 1350. Many of Defendant's remaining arguments center around the lack of disclosed structure, but the detailed recitation of corresponding structure is not part of the review for a claim alleged to include a step-plus-function limitation and Defendant identifies no applicable case law concluding otherwise. See Joint Br. at 65–68.

In a pivot to arguing a step-plus-function limitation, Defendant avers that § 112(f) applies absent express step-plus-function language when an element recites only an underlying function without acts. Joint Br. at 73–74 (citing Seal-Flex, Inc., 173 F.3d at 849–50 (Rader, J., concurring). Even applying the proposed approach contained in Judge Rader's Seal-Flex, Inc. concurrence, Defendant would not prevail in its arguments that the disputed language of Claim 1 is indefinite and invalid. Judge Rader acknowledged that distinguishing an act from a function is complicated when both are described with verbs that end in "-ing." Id. at 849. The disputed language here avoids this ambiguity because it aims "to identify a plurality of cells from the slide image," and accomplishes this function by the act of "executing at least one cell segmentation process on the slide image through the processing device." '376 Patent at 8:19–21. Defendant's remaining cite to a single, out-of-district case is inapt. Joint Br. at 73–74 (citing Agere Sys. V. Amtel Corp, No 02-864, 2003 WL 21652264, at 21–22 (E.D. Pa. May 23,

2003)). In that case, the claim language in question, "wherein said deposition temperature and environment is controlled such that," was deemed subject to § 112(f) because no further guidance was provided as to how the temperature and environment were controlled. Id. Here, the claim language specifies sufficiently the act necessary to achieve the function.

Accordingly, the Court rejects Defendant's arguments that the disputed claim language is subject to the requirements of § 112(f). The plain and ordinary meaning of the terms applies.

ii. "analyzing the plurality of cells with at least one cell classification algorithm through the processing device . . ."

The method described in Claim 1 involves "analyzing the plurality of cells with at least one cell classification algorithm through the processing device in order to identify a tumor cell percent positivity value and an immune cell percent positivity value[.]" '376 Patent at 8:22–25. Defendant asserts that the Court should construe "analyzing the plurality of cells with at least one cell classification algorithm through the processing device" under § 112(f) and should conclude that the claim language is indefinite for lack of sufficient structure. Joint Br. at 74. Similar to the "executing" limitation discussed previously, Defendant contends that the term "analyzing" is a nonce word that evidences a means-plus-function

limitation lacking in any definition of corresponding structure. Id. at 75–77, 79. Plaintiff asserts that the claim language should not be construed under § 112(f) and that the plain and ordinary meaning should apply. Id. at 74–75, 77–79. As with the preceding term, the Court notes that this dispute does not concern construction of the claim language but whether the language is subject to § 112(f).

The Court must independently review each limitation of each claim to determine whether it is subject to the requirements of § 112(f). Generation II Orthotics, Inc. v Medical Techs., Inc., 263 F.3d 1356, 1368 (Fed. Cir. 2001).

The disputed claim language is similar to the preceding element in that it does not contain the term "step for," and therefore indicates that § 112(f) was not intended to apply. See Cardiac Pacemakers, Inc., 381 F.3d at 1381–82. Applying Judge Rader's proposed approach for assessing the existence of a step-plus-function limitation in the absence of express step-plus-function language, the claim is still not subject to the requirements of § 112(f) because reading the limitation's language in its entirety reveals that it aims "to identify a tumor cell percent positivity value and an immune percent positivity value" and accomplishes this function by the act of "analyzing the plurality of cells with at least one cell classification algorithm through the processing device." See Seal-Flex, Inc., 173 F.3d at 849–50 (Rader, J., concurring).

Defendant's indefiniteness arguments misstate the applicable law. See O.I. Corp., 115 F.3d at 1583. Defendant contends that the disputed claim language "is properly construed as means-plus-function language," and argues that "analyzing" is a nonce term that precedes a functional description that lacks mention of the correlating algorithm or structure. Joint Br. at 76–77. Defendant's sur-reply position refers to the disputed claim language as "a step-plus-function limitation, the analysis of which is governed by Williamson and similar precedent." Id. at 79. Most of Defendant's arguments refer to its prior assertions regarding Williamson and related case law for the preceding element. The Court similarly concludes that there is no indication that the law governing means-plus-function claim limitations is intended to govern step-plus-function claim limitations.

The Court concludes that the claim language "analyzing the plurality of cells with at least one cell classification algorithm through the processing device" is not subject to the requirements of § 112(f). The plain and ordinary meaning of the terms applies.

iii. "an automated slide scanning system and a processing device . . ."

The first element in the method described in Claim 1 recites "providing an automated slide scanning system and a processing device wherein the automated slide scanning system comprises an image acquisition unit, and wherein the

automated slide scanning system is electronically connected to the processing device[.]" '376 Patent at 8:9–13.

Defendant asserts that "an automated slide scanning system and a processing device" should be construed to mean "a system that scans a tissue sample on a microscope slide and analyzes the cells on the tissue sample without human intervention." Joint Br. at 80. Defendant argues that the written description indicates that the functions of the slide scanning system and the cell analysis functions performed on the processing device are both automated. Id. at 82–84, 85.

Plaintiff argues that "an automated slide scanning system and a processing device" should be given its plain and ordinary meaning, or in the alternative, should be construed as "a system that provides automated scanning of a slide and a processing device." Id. at 80. Plaintiff contends that the grammatical structure of the claim language indicates that "automated" modifies only the slide scanning system but not the processing device. Id. at 80–81, 84.

Descriptions of "the present invention" as a whole may limit the scope of the invention, but use of this phrase is not always limiting when the references are not consistent or when portions of the intrinsic evidence do not support applying the limitation to the entire patent. Compare Verizon Servs. Corp. v. Vonage Holdings Corp., 503 F.3d 1295, 1308 (Fed. Cir. 2007) ("When a patent thus describes the

features of the 'present invention' as a whole, this description limits the scope of the invention.") with Absolute Software, Inc. v. Stealth Signal, Inc., 659 F.3d 1121, 1136–37 (Fed. Cir. 2011) ("we have found that use of the phrase 'present invention' or 'this invention' is not always so limiting, such as where the references to a certain limitation as being the 'invention' are not uniform, or where other portions of the intrinsic evidence do not support applying the limitation to the entire patent."). Claim terms requiring automation or automatic functionality are often construed as a process or action that is completed without human intervention, though as a practical matter, some degree of non-essential human interruption or intervention may be possible or required (e.g., to turn on an automatic machine) without negating the automatic goals of the claimed invention. Rembrandt Patent Innovations, LLC, 716 Fed.Appx. at 972; Vehicle IP, LLC v. Werner Enterprises, Inc., 4 F. Supp. 3d 648, 658–63 (D. Del. 2013).

The '376 Patent discusses existing challenges in digital pathology and states in the "Background of the Invention" section that "there remains a need for" an algorithm that addresses "fully automated analytics" integrated into a slide scanner in a variety of ways. '376 Patent at 2:12–25. The specification states that "the present invention is a method of predicting the potential effectiveness of one or more immunotherapy approaches in a given patient through automated slide scanning and image analysis of a tissue sample from a patient," and that "[t]he

present invention provides a consolidated system of various sectors: whole slide scanning, image acquisition, image management, and image interpretation and analysis through various algorithms . . . ." Id. at 2:60–3:9. The specification provides further that "[v]arious algorithms utilized by the present invention may be trained through machine learning to ensure more accurate results." Id. at 3:7–9. These references and the described functions of the processing device indicate that the claimed method requires automation of the slide scanning system and the cell analysis functions accomplished by the processing device.

Although the specification acknowledges that a technician, pathologist, or pathology assistant could manually perform the automated detection feature, the overall descriptions of the present invention are not directed to a method that requires human intervention for the cell analysis feature. See id. at 3:5–4:9, 4:25–29. Rather, the focus of the '376 Patent is on an automated process that provides an advancement over past methods implemented manually and aims to "provide a more comprehensive assessment and an aid for the pathologists to provide more accurate quantification of biomarkers." Id. at 1:45–61.

Defendant's proposed construction defines "automatically" as "without human intervention," however the '376 does not prohibit or disclaim all human involvement and instead contemplates a degree of human initiation or interruption that can occur without altering the automated aspect of the solution. See

CollegeNet, Inc. v. ApplyYourself, Inc., 418 F.3d 1225, 1235 (Fed. Cir. 2005) (rejecting defendant's construction of "automatically" as "without human intervention" as too preclusive because the claim language did not prohibit human interaction entirely to initiate automated functions). Accordingly, the Court concludes that for the "automatic" descriptions of the present invention to provide a meaningful limitation, it must require that the slide scanning and cell analysis functions of the present invention are performed by machine without the requirement for human intervention, but that a human may interrupt or intervene to provide the necessary inputs for the machine(s) to perform the claimed function. Vehicle IP, LLC, 4 F. Supp. 3d at 660–63 (citing CollegeNet, Inc., 418 F.3d at 1235 (analogizing automatic processes that contemplate human intervention such as an automatic dishwasher which "automatically" washes dishes but must be loaded and turned on by a human)). Because the processing device may require several inputs or triggers to achieve its automated functions as opposed to a clear act that begins the process, the Court will not use the phrase "once initiated" in its construction to signal that the claimed automatic functions may be started by a human. Id. at 662. Rather, the Court concludes that the phrase "at a predetermined point in operation" clarifies that the automatic process occurs "when the machine has all of the algorithms and inputs necessary to perform the claimed function, regardless of the order in which it obtains that information." Id.

Considering the language of the claim, read in light of the specification, the Court construes the claim language "an automated slide scanning system and a processing device" to mean "a system that scans a tissue sample on a microscope slide and analyzes the cells on the tissue cell, without the need for human intervention at a predetermined point in operation."

iv. "an automated method of predicting efficacy of immunotherapy approaches . . ."

The preamble of Claim 1 recites "[a]n automated method of predicting the efficacy of immunotherapy approaches comprises the steps of . . . ." '376 Patent at 8:7–8. Defendant asserts that the Court should construe "an automated method of predicting the efficacy of immunotherapy approaches" to mean "the recited steps of the method are carried out without human intervention." Joint Br. at 85. Defendant argues that the preamble is limiting because the specification uses the words of the preamble to define the purpose of the invention as fully automated. Id. at 89–91. Defendant also points to Plaintiff's prevailing arguments during the motion to dismiss stage, which emphasized that even if manual processes could define tumor and non-tumor regions, it is the automated functionality of the claimed consolidated system that provides more accurate diagnoses and represents a technical improvement. Oral Arg. Tr. at 120:36–122:27; see also OptraSCAN's Answering Br. Opp. Morphle Labs Inc.'s Mot. Dismiss for Failure to State a Claim

(D.I. 20) at 3–5; Opinion and Order Denying Mot. to Dismiss (D.I. 32) at 14–16 ("The Court concludes that the '376 Patent represents an improvement over the prior art because it combines, in one system, cell segmentation and cell classification to produce a more accurate treatment efficacy score[, and t]he consolidated system is not only automated and streamlined, but it is also more accurate and more efficient in recommending treatment.").

Plaintiff asserts that the preamble is not limiting, and the Court should construe "an automated method of predicting the efficacy of immunotherapy approaches" to mean "a method of predicting efficacy of immunotherapy that uses automation." Joint Br. at 86. Plaintiff argues that the body of Claim 1 describes a structurally complete invention and the preambular language is not necessary to interpret the claim. Id. at 85–88. In the alternative, Plaintiff proposes that the language should not be interpreted as "fully automated" but only requiring some automation because certain steps do not require automation without human intervention. Id. at 88–89.

Preambular language can be limiting when it recites additional steps or structure underscored as important in the specification, or gives "life, meaning, and vitality" to the claim, or if it is relied upon in prosecution to distinguish the claimed invention from prior art. Catalina Marketing Int., Inc. v.

Coolsavings.com, Inc., 289 F.3d 801, 808–810 (Fed. Cir. 2002); Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305 (Fed. Cir. 1999).

Neither Party disputes that the preambular language was irrelevant to the prosecution history. The Court observes that the preambular language, "[a]n automated method of predicting the efficacy of immunotherapy approaches," underscores the automated functionality ascribed to the present invention in the specification, which indicates that the goal of the claimed method is to streamline and consolidate manual processes and automate such processes beyond the ability of a human to "provide a more comprehensive assessment and an aid for the pathologists to provide more accurate quantification of biomarkers." '376 Patent at 1:45–61, 2:12–25, 2:60–3:9.

Defendant's proposed construction precludes all human involvement by defining the automatic method as one that occurs "without human intervention," which limits the scope more than the '376 Patent's descriptions of the method do and could confuse a jury as to how certain steps occur. Joint Br. at 89–91. By contrast, Plaintiff's proposed construction would indicate that some steps of the claimed method are automated while other steps are performed manually, which risks overstating the nature of any human involvement in the method. Id. at 88–89. As with the preceding term, the Court observes that some human involvement may be permitted to initiate the method, such as mounting the tissue sample on the slide

or providing the slide scanning system with the slide. See '376 Patent at 8:14–16. However, these inputs and triggers are peripheral to the achievement of the claimed method's advancement in slide scanning and analysis. See Vehicle IP, LLC, 4 F. Supp. 3d at 660–63.

Accordingly, the Court construes the phrase "an automated method of predicting the efficacy of immunotherapy approaches" to mean "the recited steps of the method are carried out without the need for human intervention at a predetermined point in operation."

CONCLUSION

For the foregoing reasons, the Court construes the disputed claim terms from the '365 Patent as follows:

1. "slide basket transfer assembly" as "a component that includes a vertical structure which enables movement of a slide basket holder along the vertical structure at the Z axis";
2. "slide transfer assembly" as "structure sufficient to move an individual slide between the slide basket transfer assembly and the slide scanning stage";
3. "support base" as "structure in the slide transfer assembly that moves horizontally in an X-Y plane";

4. "slide scanning stage" as "structure on which at least one slide is placed for scanning";
5. "slide transfer assembly configured to retrieve a slide from the slide basket transfer assembly, deliver the slide to the slide scanning stage of a slide scanner, and return the slide from the slide scanning stage to the slide basket transfer assembly" as "the slide transfer assembly is able to retrieve an individual microscope slide from the slide basket transfer assembly, deliver the same individual microscope slide to the slide scanning stage of the slide scanner, and return the same individual microscope slide to the slide basket transfer assembly"; and
6. "slide holder" as "a structure that holds at least one slide in place for scanning."

The Court construes the disputed claim terms from the '376 Patent as follows:

1. "executing at least one cell segmentation process on the slide image through the processing device" has its plain and ordinary meaning;
2. "analyzing the plurality of cells with at least one cell classification algorithm through the processing device" has its plain and ordinary meaning;
3. "an automated slide scanning system and a processing device" as "a system that scans a tissue sample on a microscope slide and analyzes the

cells on the tissue cell, without the need for human intervention at a predetermined point in operation"; and

4. "an automated method of predicting the efficacy of immunotherapy approaches" as "the recited steps of the method are carried out without the need for human intervention at a predetermined point in operation."

DATED: November 20, 2025

/s/ Jennifer Choe-Groves
Jennifer Choe-Groves
U.S. District Court Judge*

*Judge Jennifer Choe-Groves, of the United States Court of International Trade, sitting by designation.